

**WE CLAIM:**

- 1    1. A storage stable fosinopril tablet comprising fosinopril and a combination of  
2        colloidal silicon dioxide and talc.
- 1    2. The storage stable tablet of claim 1, wherein the fosinopril comprises one or more of  
2        free fosinopril acid and pharmaceutically acceptable salts of fosinopril.
- 1    3. The storage stable tablet of claim 2, wherein the pharmaceutically acceptable salt of  
2        fosinopril comprises one or more of fosinopril sodium, fosinopril magnesium and  
3        fosinopril calcium.
- 1    4. The storage stable tablet of claim 3, wherein the pharmaceutically acceptable salt  
2        comprises fosinopril sodium.
- 1    5. The storage stable tablet of claim 1, wherein the colloidal silicon dioxide comprises  
2        from about 0.25% to about 10% by weight of the total tablet weight.
- 1    6. The storage stable tablet of claim 1, wherein the talc comprises from about 0.25% to  
2        about 5% by weight of the total tablet weight.
- 1    7. The storage stable tablet of claim 1, wherein the tablet further comprises one or more  
2        pharmaceutically acceptable excipients.
- 1    8. The storage stable tablet of claim 7, wherein the one or more pharmaceutically  
2        acceptable excipients comprise one or more of diluent, disintegrant, binder, coloring  
3        agent, and flavoring agent.
- 1    9. The storage stable tablet of claim 8, wherein the diluent comprises one or more of  
2        calcium carbonate, calcium phosphate-dibasic, calcium phosphate-tribasic, calcium  
3        sulfate, cellulose-microcrystalline, cellulose powdered, dextrates, dextrans, dextrose  
4        excipients, fructose, kaolin, lactitol, lactose, mannitol, sorbitol, starch, starch  
5        pregelatinized, sucrose, sugar compressible and sugar confectioners.
- 1    10. The storage stable tablet of claim 9, wherein the diluent comprises lactose.
- 1    11. The storage stable tablet of claim 8, wherein the binder comprises one or more of  
2        methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose,

- 3 polyvinylpyrrolidone, gelatin, gum arabic, ethyl cellulose, polyvinyl alcohol,  
4 pullulan, pregelatinized starch, agar, tragacanth, alginic acid derivatives and  
5 propylene glycol, and alginate.
- 1 12. The storage stable tablet of claim 11, wherein the binder comprises  
2 polyvinylpyrrolidone.
- 1 13. The storage stable tablet of claim 8, wherein the disintegrant comprises one or more  
2 of low substituted hydroxypropyl cellulose, carboxymethyl cellulose, calcium  
3 carboxymethyl cellulose, sodium carboxymethyl cellulose, croscarmellose sodium,  
4 starch, crystalline cellulose, hydroxypropyl starch, and partly pregelatinized starch.
- 1 14. The storage stable tablet of claim 13, wherein the disintegrant comprises  
2 croscarmellose sodium.
- 1 15. The storage stable tablet of claim 1, wherein the tablet further comprises one or more  
2 additional active ingredients.
- 1 16. The storage stable tablet of claim 15, wherein the one or more additional active  
2 ingredients comprise a diuretic comprising one or more of chlorthalidone,  
3 furosemide, triameterene, amiloride, spironolactone, and thiazide diuretics.
- 1 17. The storage stable tablet of claim 16, wherein the thiazide diuretic comprises one or  
2 more of chlorothiazide, hydrochlorothiazide, flumethiazide and  
3 bendroflumethiazide.
- 1 18. The storage stable tablet of claim 17 wherein the thiazide diuretic comprises  
2 hydrochlorothiazide.
- 1 19. The storage stable tablet of claim 15, wherein the one or more additional active  
2 ingredients comprise one or more of antidepressants, antidiabetics, antiulcers,  
3 analgesics, antihypertensives, antibiotics, antipsychotics, antineoplastics,  
4 antimuscarinics, diuretics, antimigraine agents, antivirals, anti-inflammatory agents,  
5 sedatives, antihistaminics, antiparasitic agents, antiepileptics and lipid lowering  
6 agents.

- 1       20. The storage stable tablet of claim 15, wherein the one or more additional active  
2       ingredients comprise one or more of enalapril, captopril, benazepril, lisinopril,  
3       ranitidine, famotidine, ranitidine bismuth citrate, diltiazem, propranolol, verapamil,  
4       nifedipine, acyclovir, ciprofloxacin, simvastatin, atorvastatin, lovastatin, divalproex,  
5       venlafaxine, citalopram, paroxetine, selegiline, midazolam, fluoxetine, acarbose,  
6       buspirone, nimesulide, captopril, nabumetone, glimepiride, glipizide, etodolac,  
7       nefazodone and their pharmaceutically acceptable salts.
- 1       21. The storage stable tablet of claim 1, wherein greater than approximately 98% of an  
2       initial amount of fosinopril sodium remains after storage for three months at 40°C  
3       and 75% relative humidity as measured by high performance liquid chromatography.
- 1       22. The storage stable tablet of claim 1, wherein greater than approximately 98% of an  
2       initial amount of fosinopril sodium remains after storage for one week at 60°C as  
3       measured by high performance liquid chromatography.
- 1       23. The storage stable tablet of claim 22, wherein greater than approximately 99% of an  
2       initial amount of fosinopril sodium remains after storage for one week at 60°C as  
3       measured by high performance liquid chromatography.
- 1       24. The storage stable tablet of claim 1, wherein greater than approximately 98% of an  
2       initial amount of fosinopril sodium remains after storage for one week at 60°C as  
3       measured by high performance liquid chromatography.
- 1       25. The storage stable tablet of claim 7, wherein the tablet comprises approximately 20%  
2       by weight of fosinopril sodium, approximately 45% by weight of anhydrous lactose,  
3       approximately 20% by weight of microcrystalline cellulose, approximately 3.5% by  
4       weight of crospovidone, approximately 5% by weight of polyvinylpyrrolidone,  
5       approximately 2.5% by weight of colloidal silicon dioxide, and approximately 4.0%  
6       by weight of talc.
- 1       26. A storage stable fosinopril tablet comprising:  
2           from about 1% to about 40% by weight fosinopril sodium;  
3           up to 25% by weight of a diuretic;

- 4       from about 20% to about 85% by weight of diluent;
- 5       from about 1% to about 10% by weight of disintegrant;
- 6       from about 1% to about 10% by weight of binder;
- 7       from about 0.25% to about 10% by weight of colloidal silicon dioxide; and
- 8       from about 0.25% to about 5% by weight of talc,
- 9       wherein the weights are percentages of the total tablet weight.
- 1     27. A process for preparing storage stable fosinopril tablets, the process comprising the  
2       steps of:
- 3       a. blending fosinopril in one or more of its free acid form and its  
4           pharmaceutically acceptable salts with one or more pharmaceutically  
5           acceptable excipients to form a blend,
- 6       b. optionally granulating the blend to form granules;
- 7       c. lubricating the blend or granules with colloidal silicon dioxide and talc; and
- 8       d. compressing into tablets.
- 1     28. The process according to claim 27, further comprising granulating the blend of step  
2       (a).
- 1     29. The process according to claim 28, wherein granulating the blend of step (a)  
2       comprises a wet granulation process.
- 1     30. The process according to claim 28, wherein granulating the blend of step (a)  
2       comprises a dry granulation process.
- 1     31. The process according to claim 27, wherein the blend of step (a) further comprises  
2       one or more additional active ingredients.
- 1     32. The process according to claim 31, wherein the additional active ingredient  
2       comprises one or more of a diuretic comprising chlorthalidone, furosemide,  
3           triameterene, amiloride, spironolactone, and thiazide diuretics.
- 1     33. The process according to claim 32, wherein the thiazide diuretic comprises one or  
2       more of chlorothiazide, hydrochlorothiazide, flumethiazide and  
3           bendroflumethiazide.
- 1     34. The process according to claim 33, wherein the thiazide diuretic comprises

- 2       hydrochlorothiazide.
- 1   35. The process according to claim 27, further comprising using high performance liquid  
2       chromatography to measure the amount of fosinopril after storage.
- 1   36. The process according to claim 35, wherein greater than approximately 98% of an  
2       initial amount of fosinopril remains after storage for three months at 40°C and 75%,  
3       the amount of fosinopril being measured by high performance liquid  
4       chromatography.
- 1   37. The process according to claim 35, wherein greater than approximately 99% of an  
2       initial amount of fosinopril remains after storage for one week at 60°C, the amount  
3       of fosinopril being measured by high performance liquid chromatography.
- 1   38. A method for one or more of treating hypertension in a mammal and the  
2       management of heart failure as an adjunctive therapy in a mammal, the method  
3       comprising administering to the mammal one or more fosinopril tablets comprising  
4       fisinopril in one or more of its free acid form and its pharmaceutically acceptable  
5       salts, colloidal silicon dioxide, and talc.
- 1   39. The method according to claim 38, wherein the tablet further comprises a second  
2       active ingredient.
- 1   40. The method according to claim 39, wherein the second active ingredient comprises a  
2       diuretic comprising one or more of chlorthalidone, furosemide, triameterene,  
3       amiloride, spironolactone, and thiazide diuretics.
- 1   41. The method according to claim 40, wherein the thiazide diuretic comprises one or  
2       more of chlorothiazide, hydrochlorothiazide, flumethiazide and  
3       bendroflumethiazide.
- 1   42. The method according to claim 41, wherein the thiazide diuretic comprises  
2       hydrochlorothiazide.
- 1   43. The method according to claim 38, wherein greater than approximately 98% of an  
2       initial amount of fosinopril remains after storage for three months at 40°C and 75%  
3       relative humidity as measured by high performance liquid chromatography.

- 1    44. The storage stable tablet of claim 38, wherein greater than approximately 99% of an  
2    initial amount of fosinopril sodium remains after storage for one week at 60°C as  
3    measured by high performance liquid chromatography.